

REMARKS

Claims 1-23 were pending. Applicants amend Claims 1-23 and add new Claims 24-40. The amendments and the new claims do not add any new matter. The amended and the new claims are based on the originally filed claims and are further supported throughout the application, as filed. For example, in reference to U.S. Patent Application Publication US 2006/0096504, new Claims 25 and 30 are supported in paragraph 0011, new Claims 38 and 40 are based on previously presented claims and also supported in paragraph 0029, and certain amendments to Claim 1 are supported in paragraph 0012. Applicants also amend the specification and the claims to correct the informalities and for clarification. Claims 1-40 will be pending upon entry of the amendments.

Claim Rejections under 35 U.S.C. §102(b)

U.S. Patent No. 5,342,441 to Mandai *et al.*

The Office Action rejects Claims 1-19 under 35 U.S.C. §102(b) in light of U.S. Patent No. 5,342,441 to Mandai *et al.* (“*Mandai*”). Applicants assert that Mandai fails to anticipate Claims 1-19 or any other pending claims. Anticipation requires the cited reference to teach each and every element of the claim. *See* MPEP 2131.01. *Mandai* does not teach at least one element of a composition recited in Claim 1, “a liquid component comprising pyrophosphate ions and water.” Accordingly, *Mandai* fails to anticipate Claims 1 and any of its dependent claims for at least this reason. Furthermore, *Mandai* also fails to anticipate new Claims 24-34 at least because *Mandai* does not teach at least one element of a composition recited in these claims, “a liquid component comprising pyrophosphoric acid, orthophosphoric acid and water.”

In Claim 1, cited by the Examiner on page 3 of the Office Action, *Mandai* discloses “[a] hardenable, biocompatible composition for repairing living tissue” comprising a powder component and a liquid component. Unlike the liquid component recited in the pending claims, the liquid component disclosed in Claim 1 in *Mandai* contains “a secondary phosphate ion,” and not pyrophosphate. In column 3, lines 40-43, *Mandai* teaches that “secondary [phosphate] ion

sources are selected from water-soluble secondary phosphates such as disodium, dipotassium, and diammonium hydrogen phosphates.” *Mandai* fails to teach or suggest a liquid component comprising pyrophosphate ions or pyrophosphate. The only time *Mandalai* mentions pyrophosphate is in a process for preparation of a solid tetracalcium component (*Mandalai*, Example 1, in particular, column 7, line 24 and lines 36-37). Furthermore, contrary to what the Examiner asserts on page 3 of the Office Action, *Mandalai* does not disclose or suggest a pyrophosphate ion source in Tables 1-7.

Accordingly, Applicants assert that *Mandalai* fails to teach at least one element of the pending Claims 1-19 and fails to anticipate the claims. Applicants request withdrawal of the rejection of Claims 1-19 under 35 U.S.C. §102(b) in light of *Mandalai*.

U.S. Patent No. 6,537,589 to Chae *et al.*

The Office Action rejects Claims 21 and 23 under 35 U.S.C. §102(b) in light of U.S. Patent No. 6,537,589 to Chae *et al.* (“*Chae*”). Applicants assert that *Chae* fails to anticipate Claims 21 and 23 or any other pending claims. Anticipation requires the cited reference to teach each and every element of the claim. *See* MPEP 2131.01. *Chae* does not teach at least one element of a composition recited in Claims 21 and 23, “a liquid component comprising pyrophosphate ions and water.” Accordingly, *Chae* fails to anticipate Claims 21, 23 and any other pending claims reciting the above limitation. Furthermore, *Chae* also fails to anticipate new Claims 24-34 at least because *Chae* does not teach at least one element of a composition recited in these claims, “a liquid component comprising pyrophosphoric acid, orthophosphoric acid and water.”

In Claims 1 and 5, cited by the Examiner on page 4 of the Office Action, *Chai* discloses “[a] hardenable, biocompatible composition for repairing living tissue” comprising a calcium phosphate cement and a polyphosphate. Unlike the bone cement recited in the pending Claims 21 and 23, calcium phosphate cement disclosed in *Chae* does not contain a liquid component comprising pyrophosphate. Furthermore, *Chae* does not teach or suggest a calcium phosphate cement comprising a liquid component. For example, in column 10, lines 52-55,

Chae teaches a process of producing a calcium phosphate cement that includes the steps of mixing solid ingredients and autoclaving them “wrapped in aluminum foil,” but does not indicate that any liquid components are included in the cement. *Chae* also fails to teach or suggest pyrophosphate in any form as a component of the calcium phosphate cement or “biocompatible composition” or “artificial bone” that it discloses. In particular, the polyphosphate disclosed in *Chae* as a component of “artificial bone” or “biocompatible composition” comprises 3-200 orthophosphate molecules, as acknowledged on page 4 of the Office Action (*Chae*, column 1, lines 15-16, column 10, lines 20-24, and Claim 5). Polyphosphate as disclosed by *Chae* is therefore different from pyrophosphate recited in the pending claims at least because pyrophosphate comprises two orthophosphate molecules (see dictionary definition attached as Exhibit A).

Accordingly, Applicants assert that *Chae* fails to teach at least one element of the pending Claims 21 and 23 and fails to anticipate the claims. Applicants request withdrawal of the rejection of Claims 21 and 23 under 35 U.S.C. §102(b) in light of *Chae*.

Claim Rejections under 35 U.S.C. §103(a)

U.S. Patent No. 5,342,441 to Mandai *et al.* in view of U.S. Patent No. 6,537,589 to *Chae et al.*

The Office Action rejects Claim 20 under 35 U.S.C. §102(b) in light of U.S. Patent No. 5,342,441 to Mandai *et al.* (“Mandai”) in view of U.S. Patent No. 6,537,589 to *Chae et al.* (“*Chae*”). A *prima facie* case of obviousness based on a reference or references must meet three basic criteria: (1) suggestion or motivation to modify the reference or to combine the references’ teachings; (2) a reasonable expectation of success from such a combination or modification; and, (3) the reference or references must teach or suggest all the claim limitations. See MPEP 2141.01(a) and 2142. The rejection based on a combination of Mandai and *Chae* does not meet at least one of the required *prima facie* obviousness criteria, showing of the teaching or suggestion in the references of all the claim limitations. As discussed in the previous section, Mandai or *Chae* do not teach at least one

element of a composition recited in Claim 20, “a liquid component comprising pyrophosphate ions and water.” Furthermore, *Mandai* or *Chae* fail to suggest this element of the claim. Thus, *Mandai* or *Chae*, separately or in combination, fail to render Claim 20 obvious for at least the above reason. Applicants therefore request withdrawal of the rejection of Claim 20 under 35 U.S.C. §103(a) in light of *Manlai* in view of *Chae*.

U.S. Patent No. 6,537,589 to Chae et al. in view of U.S. Patent 4,880,610 to Constanz

The Office Action rejects Claim 22 under 35 U.S.C. §102(b) in light of U.S. Patent No. 6,537,589 to Chae et al. (“*Chae*”) in view of U.S. Patent No. 4,880,610 to Constanz (“*Constanz*”). A *prima facie* case of obviousness based on a reference or references must meet three basic criteria: (1) suggestion or motivation to modify the reference or to combine the references’ teachings; (2) a reasonable expectation of success from such a combination or modification; and, (3) the reference or references must teach or suggest all the claim limitations. See MPEP 2141.01(a) and 2142. The rejection based on a combination of *Chae* and *Constanz* does not meet at least one of the required *prima facie* obviousness criteria, showing of the teaching or suggestion in the references of all the claim limitations.

As discussed in the previous sections, *Chae* does not teach or suggest at least one element of a composition recited in Claim 22, “a liquid component comprising pyrophosphate ions and water.” As discussed by the Examiner on page 5 of the Office Action, *Constanz* discloses hardenable calcium phosphate materials. However, *Constanz* fails to teach or suggest a material comprising a liquid component comprising pyrophosphate ions or pyrophosphate. Accordingly, *Chae* or *Constanz*, separately or in combination, fail to teach or suggest at least one element of Claim 20 and fail to render the claim obvious. Applicants therefore request withdrawal of the rejection of Claim 22 under 35 U.S.C. §103(a) in light of *Chae* in view of *Constanz*.

CONCLUSION

In light of the amendments and the above remarks, Applicants are of the opinion that the application is now in condition for allowance. Such action is respectfully requested.

If the Examiner believes any informalities remain in the application that may be corrected by Examiner's Amendment, or there are any other issues that can be resolved by telephone interview, a telephone call to the undersigned agent at (404) 815-6102 is respectfully requested.

Respectfully submitted,

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pyrophosphate

One entry found.

pyrophosphate

Main Entry: **py-ro-phos-phate** 

Pronunciation: \-'fās-,fāt\

Function: *noun*

Date: 1833

: a salt or ester of **pyrophosphoric acid**

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pyrophosphoric

One entry found.

pyrophosphoric acid

Main Entry: **py-ro-phos-pho-ric acid** **ⓘ**

Pronunciation: \-fās-ˈfōr-ik-, -ˈfār-, -ˈfās-f(ə)-rik-\

Function: *noun*

Etymology: International Scientific Vocabulary

Date: 1832

: a crystalline acid $H_4P_2O_7$ formed when orthophosphoric acid is heated or prepared in the form of salts by heating acid salts of orthophosphoric acid

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